

Restriction of the claims in the present application has been required by the Examiner under 35 U.S.C. § 121 and § 372. In particular, the Examiner believes that the application contains certain species of the invention that are not so linked as to form a single inventive concept under PCT Rule 13.1. The Examiner has required Applicant to elect a single species of the invention for substantive examination in reply to this action.

The species of invention as set forth by the Examiner are as follows:

1) Dendritic cells from skin, spleen, bone marrow, thymus, lymph nodes, umbilical cord blood, or peripheral blood.

2) The dendritic cell maturation agent Bacillus Calmette-Gurien (BCG), interferon  $\gamma$  (INF $\gamma$ ), lipopolysaccharide (LPS), tumor necrosis factor  $\alpha$  (TNF $\alpha$ ), an imidazoquinoline compound, a synthetic double stranded polyribonucleotide, an agonist of a Toll-receptor (TLR), a sequence of nucleic acids containing unmethylated CpG motifs, or any combination thereof.

3) Co-stimulatory molecules CD80, CD86 and/or CD54.

The Examiner alleges that the recited species do not relate to a single general inventive concept under PCT Rule 13.1 because, under PCT Rule 13.2 the species lack the same or corresponding technical feature. In particular, the Examiner believes that the species:

1) dendritic cells from skin, spleen, bone marrow, thymus, lymph nodes, umbilical cord blood, or peripheral blood are from different organs and do not share the same properties;

2) Bacillus Calmette-Gurien (BCG), interferon  $\gamma$  (INF $\gamma$ ), lipopolysaccharide (LPS), tumor necrosis factor  $\alpha$  (TNF $\alpha$ ), an imidazoquinoline compound, a synthetic double stranded polyribonucleotide, an agonist of a Toll-receptor (TLR), a sequence of nucleic acids containing unmethylated CpG motifs, or any combination thereof do not share the same structure and properties; and

3) CD80, CD86 and/or CD54 do not share the same structure or properties.

Applicant traverses the instant request to restrict the claims of the present invention for substantive examination. Prior to stating the reasons for traverse, as required Applicant elects for further substantive prosecution the following species:

- 1) dendritic cells isolated from peripheral blood;
- 2) BCG and interferon  $\gamma$  as the dendritic cell maturation agent; and
- 3) CD86 as the co-stimulatory molecule.

Restriction is not believed to be required in the present application because each of the species list by the Examiner share functional properties in the context of the present invention. The present invention relates to methods for the use of partially mature dendritic cells for producing an anti-tumor immune response in an individual with a tumor. The partially matured dendritic cells can be generated from immature dendritic cells or dendritic cell precursors obtained from skin, spleen, bone marrow, thymus, lymph nodes, umbilical cord blood, or peripheral blood. All of the immature dendritic cells or dendritic cell precursors share the same properties in that they are capable of uptake and processing an antigen for presentation to T cells and as such can be induced to mature into mature dendritic cells. The compositions of the present invention comprise dendritic cells that have not been fully matured *in vitro*. Maturation of immature dendritic cells can be induced using one of a number of dendritic cell maturation agents. The maturation agents do not all share the same chemical structure, but do share the common functional feature of being capable of inducing immature dendritic cells to mature. The agents identified by the Examiner as species (2) comprise a number of dendritic cell maturation agents that are known to the skilled artisan. Partially mature dendritic cells can be distinguished from immature dendritic cells by an increase in expression of any one of three cell surface co-stimulatory molecules, CD80, CD86 and/or CD54. The Examiner has also required election of one of these three molecules as species (3). As the expression of the c-stimulatory molecules is induced by any of the maturation agents, election of only one of the co-stimulatory molecules is not understood.

Therefore, contrary to the allegation of the Examiner the species as designated by the Examiner do share a common technical feature in that they share a common function in the general concept of the present invention. Applicant believes that the requirement for restriction in the present application will prevent the claiming of the entire inventive concept as set forth and further, will not result in a compact prosecution. Applicant notes that the Examiner has not indicated that any claim is generic. Nor has the Examiner indicated that the election of species to which the claims shall be restricted is only necessitated if no generic claim is finally held to be allowable and that upon allowance of a generic claim, Applicant will be entitled to consideration of claims to additional species which are written in dependent form or otherwise include all the limitations of an allowed generic claim as provided by 37 CFR § 1.141. Applicant notes that claims 1-10, and 13-32 encompass the elected invention.

Applicant notes that claim 32 has been amended to recite "the composition according to claim 21" to make it consistent with the claim from which it depends.

As set forth above, Applicant believes all requirements for responding to the restriction requirement have been addressed. Applicant respectfully requests reconsideration of the request for species election. If a telephone conference would expedite this matter, the Examiner is respectfully encouraged to contact the undersigned at 206-467-9600.

Respectfully submitted,

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